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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,017

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EXAMINER

BUCKLEY, AUDREA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,017	Applicant(s) ANDERSEN, THORKILD	
	Examiner AUDREA BUCKLEY	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 2, 8, and 9, in the reply filed on July 14, 2009 is acknowledged, and these claims are examined on the merits herein.

Claims 3-7 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected insert made of a moldable material, contact lenses, and the use of silver nanoparticles and/or a titanium oxide photocatalyst, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 14, 2009.

Priority

This application claims priority to PCT/DK05/00178, filed March 17, 2005.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. These papers claim the filing date of Denmark Patent Application No. 200400432, filed March 17, 2004.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 15, 2006 was filed after the mailing date of the application on September 18, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanderlaan *et al.* (US 2002/0197299 A1).

Regarding claims 1 and 8, Vanderlaan *et al.* teach antimicrobial contact lenses and containers which comprise nanosize silver powder as an antibacterial agent. The containers are made of thermoplastic polymeric material structured from a mold (page 2, column 2, [0016]) and may be adapted to define a space in which to hold a lens (page 2, column 2, [0014]). It is specified that the lens container, the lens basket, or the top of the lens container may contain activated silver (page 3, column 1, [0018]) and the method for implementing the silver active agent into the polymeric molded article which is the antimicrobial lens container or its components is the same method as disclosed for implementing the silver active agent into the antimicrobial lenses.

Since the content and limitations of the instant claims are previously taught in the disclosure of Vanderlaan *et al.*, Vanderlaan *et al.* anticipated the contents of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan *et al.* (US 2002/0197299 A1)

Regarding claims 1 and 8, Vanderlaan *et al.* teach antimicrobial contact lenses and containers which comprise nanosize silver powder as an antibacterial agent. The containers are made of thermoplastic polymeric material structured from a mold (page 2, column 2, [0016]) and may be adapted to define a space in which to hold a lens (page 2, column 2, [0014]). It is specified that the lens container, the lens basket, or the top of the lens container may contain activated silver (page 3, column 1, [0018]) and the method for implementing the silver active agent into the polymeric molded article which is the antimicrobial lens

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container or its components is the same method as disclosed for implementing the silver active agent into the antimicrobial lenses. Since the content and limitations of the instant claims are previously taught in the disclosure of Vanderlaan *et al.*, Vanderlaan *et al.* anticipated the contents of the instant claims.

As to claims 2 and 9 which limit the content of the silver concentration, Vanderlaan *et al.* teach a value of about 0.01 to about 10 weight percent, preferably about 0.05 to about 3.0 percent. So, the quantity presence of silver active agent as taught by Vanderlaan *et al.* does not exactly match that instantly claimed.

However, one of ordinary skill in the art at the time the invention was made would have performed routine optimization procedures in order to determine a presence of silver appropriate for the desired antimicrobial efficacy in the contact lens and case application. MPEP 2144.05 addresses routine optimization procedure as it relates to patentability:

“Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the

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references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).”

On account of the prior art of Vanderlaan *et al.* teaching the same inventive concept and same qualitative limitations as those instantly claimed, and on account of the inventor's motive to perform routine optimization procedures, one of ordinary skill in the art at the time the invention was made would have found the function and limitations of the antimicrobial features of the contact lens and case as instantly claimed to have been *prima facie* obvious.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Audrea Buckley/
Patent Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611